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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,035	10/08/2003	Thomas J. Felt	109-03	2719
23713	7590	02/10/2006		
GREENLEE WINNER AND SULLIVAN P C			EXAMINER	
4875 PEARL EAST CIRCLE			DEAK, LESLIE R	
SUITE 200			ART UNIT	
BOULDER, CO 80301			PAPER NUMBER	
			3761	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/681,035

Applicant(s)

FELT ET AL.

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 1-34 and 62-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/18/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-34 and 62-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1 December 2005.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 40, 43, are rejected under 35 U.S.C. 112, second paragraph, as as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 39, 40 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: components of the claimed device that measure hematocrit levels and flow rates for the calculations required by the limitations of claims 39 and 40. Applicant recites only a pressure sensor as a data-gathering component of the invention, and provides no structural means to collect hematocrit or flow rate data.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 35-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,954,971 to Pages et al in view of US 5,423,746 to Burkett et al.

In the specification and figures, Pages discloses the apparatus substantially as claimed by applicant. In particular, Pages discloses a fluid separation system with controller comprising pump 132, a fluid pressure sensor 153, a filter 140 (may be a leukocyte filter), and a microcomputer or processor within flow controller 155 (see column 4, lines 1-67). The processor may be provided with specified predetermined values (such as P_{min} , P_{max} , which are equivalent to applicant's claimed "system pressures") that are compared to a measured pressure P_a from the pressure sensor 153. If the measured pressure is outside the limits programmed into the controller, the system enters alarm state 315 in which the pump may be stopped and an alarm signal generated (see column 4, lines 52-67, column 5, lines 1-11). Pages further discloses that the alarm limit may be more complex than a single-value pressure measurement, and may comprise a series of pressure measurements made over a specified period of time (see column 5, lines 26-47).

Pages fails to disclose that the processor is programmed to count the first-level alarms and trigger a second level alarm within a specified period of accumulated first-

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level alarms. (By claiming that the processor is "programmed to" carry out the claimed steps, applicant has positively claimed the operation of the processor as a part of his device. This recitation complies with the guidelines for computer-related inventions set forth in MPEP § 2106.) However, Burkett discloses a patient infusion system that measures changes in pressure in order to detect dangerous conditions when infusing a patient with treatment fluid. In particular, Burkett discloses a system that uses a microprocessor and alarm system to indicate when the measured pressure from pressure transducer 62 exceeds a programmed value (see column 10, lines 15-67, column 11, lines 1-30). A green light indicates a functioning infusion site; a yellow light may be used to indicate an initial or transitory condition; and a red light and/or audible signal may be used to indicate that a number of consecutive tests have resulted in alarm conditions. If a selected number of yellow alarm conditions are met (such as 5), the red alarm light and an audible sound will emit from the monitor, producing a secondary alarm to indicate an urgent condition that requires immediate attention (see column 11, lines 16-30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to program the controller and microprocessor disclosed by Pages with the primary and secondary alarm sequence program disclosed by Burkett, in order to alert the operator to an urgent condition requiring immediate attention, as taught by Burkett.

With regard to claims 39 and 40, the Pages device controls an apheresis system, as claimed. However, applicant fails to claim any devices that measure hematocrit

levels or flow rates. Applicant recites only a pressure sensor as a data-gathering component of the invention, failing to provide a means to generate hematocrit or flow rate signals. Without additional structural parameters, Examiner considers the Pages device capable of performing the functions claimed by applicant, and therefore the instantly claimed invention is unpatentable over the combination of Pages and Burkett.

With regard to claims 41, 45, 46, 50-53, and 59-60, Pages and Burkett fail to disclose the specified system pressure, number of alarm signals, or delay time as claimed by applicant. However, maintaining proper pressure within an apheresis system is a result-effective variable. If the pressure falls outside an appropriate range, the apheresis system will fail or injure the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to set the acceptable system pressure to the value claimed by applicant, since it has been held that discovering the optimum value of a result-effective variable involves only routine skill in the art. See MPEP § 2144.04.

With regard to claims 43, 44, and 47, as best understood by the examiner, the Pages device may restart pumping operations once the measures pressure falls within an acceptable range of predetermined pressure values as calculated by controller 155 (see column 5, lines 12-23). Upon such correction, system leaves alarm state 315 (which comprises an audible and/or visible alarm), which means that the processor halts the alarm upon leaving the alarm state.

With regard to claims 48, 49, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an additional alarm state in

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the device disclosed by Pages, since it has been held that mere duplication of the essential working parts of a device and steps of a procedures involve only routine skill in the art. See MPEP § 2144.04.

With regard to claims 55-58, applicant sets forth limitations concerning the operation of the claimed device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

With regard to claim 61, Pages discloses controller 255 that operates the apheresis procedure as a whole, including assessing the collection of blood from the donor and completeness of the procedure. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 5,502,812 Leyre et al
 - i. Redundant fault processing alarm system
- b. US 5,652,566 Lambert
 - ii. Redundant alarm system

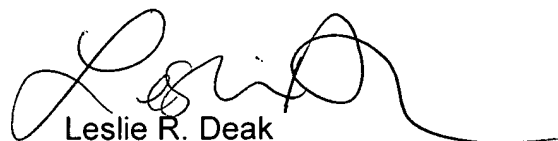
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- c. US 6,585,675 O'Mahoney et al
- iii. Extracorporeal blood circuit with primary and secondary alarms

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie R. Deak
Patent Examiner
Art Unit 3761
26 January 2006